REMARKS

THE AMENDMENTS

Following entry of this amendment, claims 46, 48, and 51-60 will be pending in this application. Claims 1-45, 47 and 49-50 are canceled.

Applicants have canceled claims 27-32, 34 and 43-44. Applicants have canceled these claims without prejudice or waiver of applicant's right to file for and obtain claims directed to any canceled subject matter in this application or in future divisional or continuing applications claiming priority from this application.

Applicants have amended claims 46 and 48 to recite a method for promoting neurite outgrowth or promoting neuronal protection against neuronal damage. Support for this amendment is provided at, e.g., specification page 4, lines 5-24; page 5, lines 5-9; page 59, line 9 to page 61, line 7; and original claim 14.

None of the amendments introduces any new matter.

THE REJECTIONS

35 U.S.C. § 112, First Paragraph - Enablement

Claims 27-32, 34, 43-44, 46, 48 and 51-60

The Examiner has rejected claims 27-32, 34, 43-44, 46, 48 and 51-60 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states that the specification, while being enabling for "up-regulating the expression of N-CAM and L1 in NG108-15 cells and increasing dendritic arbors of 7-14 DIV cultured hippocampal neurons with OP-1" and "neurite outgrowth or neuronal protection against neuronal damage caused by ischemia or caused by other mechanism such as malnutrition, anorexia or memory deficit caused by hippocampal neuronal damage or loss," does not provide

enablement for a method for reducing spatial or declarative memory dysfunction caused by damaged hippocampal tissues and caused by permanent or global ischemia comprising determining the existence of spatial or declarative memory dysfunction and administering OP-1 comprising residues 330-431 of human OP-1. The Examiner contends that memory dysfunction or deficit is a complex process and its cause or process is not clear. The Examiner further contends that the limitation "spatial or declarative memory dysfunction" is only a general term and it is not clear what is encompassed. The Examiner states that it is unpredictable whether the claimed method can truly reduce memory dysfunction. Finally, the Examiner asserts that although Li et al., J Neurosci Res., 87(1):112-22 (2009) ("Li", of record) teaches hippocampal neurogenesis induced by fluoxetine correlates with attenuation of spatial cognitive defects, neither the specification nor the prior art teaches that relationship between fluoxetine and OP-1.

Applicant traverses. First, applicant has canceled claims 27-32, 34 and 43-44, thus, rendering the rejection with respect to these claims moot.

Second, regarding Li, applicant notes that its reliance on this was to demonstrate generally that hippocampal neurogenesis is involved in improving spatial cognitive deficits. A relationship between fluoxetine and OP-1 is not necessary for a person of ordinary skill in the art to recognize that the teaching of Li is relevant to hippocampal neurogenesis induced by OP-1. Based on the disclosure of Li, one of skill in the art would reasonably believe that hippocampal neurogenesis induced by OP-1 would improve spatial cognitive deficits.

Third, applicant submits that the specification does

define what is intended by "spatial or declarative memory." At page 48, lines 15-16 the specification describes "spatial memory" as the ability to learn and remember a location using visuospatial cues. The specification at page 48, lines 17-18 also describes "declarative memory" as the ability to learn and remember associations among items or events that can be accessed flexibly to guide actions in new situations.

However, solely to expedite prosecution of this application, applicant has amended claims 46 and 48 (and therefore, claims dependent therefrom) to recite a method for promoting neurite outgrowth or promoting neuronal protection against neuronal damage. Applicant respectfully submits that the claims, as amended, are enabled by applicants' specification. Applicant has demonstrated that OP-1 induces dendritic outgrowth, differentiation and synaptogenesis. *See*, e.g., page 59, line 9 to page 61, line 7. Therefore, based on the teachings of the instant application a person of ordinary skill in the art would be able to practice the claimed methods.

For all of the above reasons, applicant respectfully requests that the Examiner withdraw this rejection.

Obviousness-type Double Patenting

Claims 27-32, 34-38, 43 and 44

The Examiner has maintained the rejection of claims 27-32, 34-38, 43 and 44 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-30 of U.S. Patent No. 6,407,060 ("the '060 patent"), issued September 30, 2008. The Examiner states that claims 1-30 of the '060 patent encompass a method for enhancing recovery of CNS

function by a morphogen comprising a conserved C-terminal seven cysteine skeleton having at least 70% homology to amino acids 330-431 of hOP-1 in a mammal suffering from a CNS injury caused by ischemia or trauma. The Examiner states that the neuronal damage in the instant claims is caused by ischemia, which is identical to the claims of the '060 patent. Further, the Examiner states that the claims of the instant application and the '060 patent encompass the same material and the same patient population which means that patients suffering from ischemia would also suffer from memory dysfunction.

Applicant traverses. However, solely to expedite prosecution of this application, applicant has canceled claims 27-32, 34-38, 43 and 44. Accordingly, the rejection is moot.

CONCLUSION

In view of the foregoing amendments and remarks, applicant requests that the Examiner reconsider and withdraw all outstanding rejections and allow the pending claims.

The Examiner is invited to telephone applicant's representatives regarding any matter that may be handled by telephone to expedite allowance of the pending claims.

Respectfully submitted,

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